

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Seiichi ARAKI Attorney Docket No.: 109536-161
Application No.: 09/943,054 Art Unit: 1614
Filing Date: August 30, 2001 Examiner Name: James D. Anderson
Reissue of: U.S. 5,945,420
Issue Date: August 31, 1999
Title: IMMUNOPOTENTIATING AND INFECTION PROTECTIVE AGENT AND PRODUCTION THEREOF

SUPPLEMENTAL DECLARATION FOR REISSUE APPLICATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

As a below named inventor, we hereby declare that:

We believe that we are the original, first and joint inventors of the subject matter which is described and claimed in patent number 5,945,420, granted August 31, 1999, and for which a reissue patent is sought on the invention entitled "Immunopotentiating and Infection Protective Agent and Production Thereof," the specification of which was filed on August 30, 2001, as reissue application number 09/943,054 and was amended on May 29, 2007.

We have reviewed and understand the contents of the above identified specification, including the claims, as amended by the amendment referred to above.

We acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR §1.56.

We believe the original patent to be wholly or partly inoperative or invalid, by reason of claiming more or less than we had the right to claim in the patent. In particular, we claimed less than we had a right to claim in the patent. This error resulted from a failure to appreciate the full scope of the invention.

More specifically, at least one error upon which reissue is based is described below, with an explanation as to the nature of the broadening reissue:

For example, one error upon which the reissue application is based is the omission of claims to a method for treating infection by administering to a patient in need of such treatment a composition comprising riboflavin and/or riboflavin derivative. None of the issued claims was directed to a method of treating an infection. Instead, the claims were directed to protection against infection by administering to a patient in need of such treatment a composition comprising riboflavin and/or riboflavin derivative.

Another example of an error upon which the reissue application is based is the omission of claims to a method of treating a patient with an infection comprising administering a composition comprising riboflavin and/or riboflavin derivative in an amount sufficient to enhance the immune function of the patient. None of the issued claims was directed to a method of treating an infection sufficient to enhance the immune function of the patient. Instead, the issued claims were directed to protection against infection by administering to a patient in need of such treatment a composition comprising riboflavin and/or riboflavin derivative.

Yet still another example of an error upon which the reissue application is based is the omission of claims to a method of enhancing the immune response of a patient with an infection by administering to the patient a composition comprising riboflavin and/or riboflavin derivative. None of the issued claims was directed to a method of enhancing the immune function of a patient with an infection. The issued claims were directed to protection against infection by administering to a patient in need of such treatment a composition comprising riboflavin and/or riboflavin derivative.

A further example of an error upon which the reissue application is based is the omission of claims to a method for treating a patient with sepsis by administering to such a patient a sufficient amount of a composition comprising riboflavin and/or riboflavin derivative. None of the issued claims were directed to a method of treating a patient that has sepsis.

Another example of an error upon which the reissue application is based is the omission of claims as are now in pending claims 1, 3-6 and 8-9. These claims are drawn to a method of enhancing the immune response to infection by *E. coli* by administration of riboflavin, flavin mononucleotide, flavin adenine dinucleotide, or pharmacologically permissible salts thereof. The originally issued claims were drawn to protection against infection by administering riboflavin and/or a riboflavin derivative. There was no claim to protection against infection caused by *E. coli*. The difference

between the originally issued claim and those now pending in claims 1, 3-6 and 8-9 is that the pending and amended claims are drawn to enhancing the immune response to infection by *E. coli*.

Another example of an error upon which the reissue application is based is the omission of claims as are now in pending claim 58, drawn to the method of claim 1 further comprising glutamine and proline. Support for this claim can be found in the originally issued patent at col. 2, lines 29-30, and Example 2. The originally issued claims did not include a claim to a method for enhancing the immune response to infection by *E. coli* in a mammal in need thereof comprising administering to said mammal a composition comprising riboflavin, flavin mononucleotide, flavin adenine dinucleotide, or pharmacologically permissible salts thereof wherein the composition further comprises glutamine and proline.

A another example of an error upon which the reissue application is based is the omission of claims as are now in claims 59-62, drawn to a method of enhancing the immune response to a virus or increasing the survival rate of a human susceptible to infection with a virus comprising administering a riboflavin and the inactivated virus. Support for these claims can be found in the specification and at Example 6 and Table 7. In the originally issued patent, there was no claim to protection against infection caused by a virus by administration of a riboflavin or a riboflavin derivative (flavin mononucleotide, flavin adenine dinucleotide, or pharmacologically permissible salts thereof) and the inactivated virus.

All errors in the present reissue application up to the time of signing of this declaration, or errors which are being corrected by a paper filed concurrently with this declaration which correction of errors we have reviewed, arose without any deceptive intention on the part of the applicants.

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor (given name, family name)

Seiichi ARAKI

Inventor's signature

Seiichi Araki

Date

Jan. 18, 2008

Residence JAPAN

Citizenship JAPAN

Mailing Address

1-35, Nagakunidai, Tsuchiurashi, IBARAKI 300-0810, JAPAN

Full name of sole or first inventor (given name, family name)

Mamoru SUZUKI

Inventor's signature

Mamoru Suzuki

Date

Jan. 18. 2008

Residence JAPAN

Citizenship JAPAN

Mailing Address

1-303, Hatsujiro, Tsukuba-shi, IBARAKI 305-0035, JAPAN

Full name of sole or first inventor (given name, family name)

Taeko FUJIMOTO (Wife of Masatoshi FUJIMOTO)

Legal Representative for Masatoshi FUJIMOTO

Inventor's signature

Taeko Fujimoto

Date

Jan. 19. 2008

Residence JAPAN

Citizenship JAPAN

Mailing Address

2-5-4, Ioukoudai, Tsukuba-shi, IBARAKI, 300-2635, JAPAN

Full name of sole or first inventor (given name, family name) Shingo FUJIMOTO (Son of Masatoshi FUJIMOTO) Legal Representative for Masatoshi FUJIMOTO	
--	--

Inventor's signature	Shingo Fujimoto	Date	Feb. 9. 2008
Residence	JAPAN	Citizenship	JAPAN

Mailing Address	4390 Clearwater Way, #2603 Lexington, KY 40515, U.S.A.
-----------------	---

Full name of sole or first inventor (given name, family name) Makiko TOTSUKA (Daughter of Masatoshi FUJIMOTO) Legal Representative for Masatoshi FUJIMOTO	
--	--

Inventor's signature	Makiko Totsuka	Date	Jan. 19. 2008
Residence	JAPAN	Citizenship	JAPAN

Mailing Address	4-1-5, Toukoudai, Tsukuba-shi, IBARAKI, 300-2635, JAPAN
-----------------	---

Full name of sole or first inventor (given name, family name) Mikiko MIZUKOSHI (Daughter of Masatoshi FUJIMOTO) Legal Representative for Masatoshi FUJIMOTO	
--	--

Inventor's signature	Mikako Mizukoshi	Date	Jan. 19. 2008
Residence	JAPAN	Citizenship	JAPAN

Mailing Address	52, Kou, Chikusei-shi, IBARAKI 308-0021, JAPAN
-----------------	--